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(54) Title: A SURGICAL SHUNT			
(57) Abstract			
<p>A surgical shunt (1) has a tubular body (2) with internal bore (3). A port (9) is provided intermediate the ends (4, 5) of the body (2) for delivery of a medical device such as a collapsible embolic protection filter (16) carried by a guidewire (17). The filter (16) is deployed downstream of the shunt (1) to entrap embolic material released during a surgical procedure. The length of the external proximal portion of a mounting system is greater than the sum of the length of the entry port (9) and a distal section of the shunt bore (3). The shunt can be completely removed while maintaining the filter (16) in place to protect against embolic material released during shunt removal.</p>			

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"A Surgical Shunt"

Introduction

5 The invention relates to a surgical shunt.

10 There are a number of well established and proven surgical procedures during which complications can arise due to the dislodgement of particulate matter such as atherosclerotic plaque from the inner surface of arteries or any encrustation from the urinary system. The dislodged particulate matter can be carried downstream and lodge in a vessel either partially or completely blocking it. Blockage of vessels can have life, limb or organ threatening consequences. One of the surgical procedures with complications of this nature is Carotid Endarterectomy. Another is the surgical treatment of Abdominal Aortic Aneurysms where embolic debris released in the lower limbs can result in the loss of feet and lower legs.

20 Carotid endarterectomy is the term given to the surgical treatment to remove plaque build up on the carotid artery, usually at the bifurcation between the common carotid artery and its two distal vessels, the internal carotid and external carotid arteries. The surgical intervention entails making an incision in the neck and exposing the carotid artery. A cut is then made in the artery itself and the vessel is clamped distally and proximally. A bypass shunt is often used to maintain blood flow to the brain during the procedure. The bypassed section of the artery is then carefully exposed and the atheroma is removed, usually with a layer of intima attached. The surgeon goes to great lengths to ensure that no particulate matter is left in the area. Localised magnification and lighting are used to provide the best possible circumstances to see extraneous material and to remove it.

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- 2 -

When the surgeon is satisfied that all the material has been removed, the exit and closure process commences. The shunt is removed carefully and the vessel is sutured closed.

5 There are a number of medical complications associated with this surgery. Some are related to the wound and the management of it. Some relate to the potential for nerve damage during the procedure. Others relate to the fact that for people with carotid bifurcations that are high, the jaw must be dislocated to allow the surgeon access to the site to be treated. Even further complications relate to the
10 fact that embolic material is sometimes released during the procedure or as is more frequently the case during and immediately after the period when the shunt is being removed and the vessel is sutured.

15 The complications being directly addressed by this invention are those associated with inadvertent release of emboli which are carried by the bloodstream into the distal cranial vasculature where they can block vessels and result in either temporary or permanent reduction of the blood supply.

20 Another example of a surgical procedure that could be enhanced by this invention is the medical procedure known as Abdominal Aortic Aneurysm (AAA) surgery. When a weakening of the Abdominal Aorta occurs, the wall of the vessel bulges. The bulge or aneurysm continues to enlarge progressively up to a point where it requires intervention or it will rupture. The most widely practised treatment for AAA is surgical. A surgical graft is sutured into position inside the aorta
25 providing an internal bypass to the defect. However, a complication associated with the procedure is that of particulate matter being carried into the lower limbs sometimes resulting in the loss of blood supply to the area. Amputation of the limb may be required in some instances. The present invention can be used to prevent this occurrence.

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- 3 -

WO 98/24377 A describes a shunt for maintaining distal blood flow during an antieromy procedure. A second tubular member is attached to the shunt through which a blood filter device is delivered. In use, the filter is deployed downstream of the shunt. The filter must be withdrawn before the shunt is removed. This may
5 result in the release of embolic material which is not filtered. In an effort to overcome this problem WO 98/24377 A describes an arrangement in which a separate introducer is used downstream of the shunt through which a filter is inserted and withdrawn. However, this complicates the procedure as additional steps and associated equipment are required.

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This invention is therefore directed towards providing a shunt which will allow a filter to remain deployed within a vessel throughout the shunting procedure.

Statements of Invention

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According to the invention there is provided a surgical shunt comprising:-

a tubular shunt body;

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an entry port integral with the shunt body;

a medical device for delivery and/or retrieval through the entry port; and

a mounting system for the medical device;

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the tubular shunt body having a bore with a proximal end and a distal section extending distally of the bore, the distal section having a distal end;

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the entry port having an external proximal section and an internal distal end communicating with the distal section of the bore;

- 4 -

the medical device mounting system having a distal portion and a proximal portion, the external proximal portion of the mounting system lying substantially external of the bore;

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the length of the external proximal portion of the mounting system being greater than the sum of the length of the entry port and the length of the distal section of the shunt bore for removal of the distal section of the shunt body while maintaining the medical device in situ.

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In a particularly preferred embodiment of the invention the mounting system comprises a medical guidewire.

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Preferably the mounting system includes a catheter for delivery and/or retrieval of the medical device, the guidewire being extendable through the catheter.

In a particularly preferred embodiment the medical device is an embolic protection device.

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In a preferred arrangement the embolic protection device comprises a filter body having;

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a first collapsed configuration and a second expanded, deployed configuration;

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a proximal inlet section and a distal outlet section, said proximal inlet section including inlet openings which are operable to admit blood and embolic material when the filter is in the second expanded configuration; and

- 5 -

a plurality of outlet openings disposed on at least a portion of the filter body adjacent to the distal outlet section, the outlet openings being sized to allow through passage of blood but to retain undesired embolic material within the filter body.

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In a preferred embodiment of the invention the filter body is mounted on the guidewire.

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Preferably the shunt includes a retrieval catheter, the guidewire being slidably movable through the catheter having a pod at a distal end thereof for reception of the filter element in a collapsed state. Preferably the pod is expandable.

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In one arrangement the pod has a resiliently deformable sidewall. In one embodiment the pod comprises radially spaced-apart reinforcing legs covered in an elastic material.

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In another embodiment of the invention the embolic protection device comprises a filter body and a delivery system for delivery and/or withdrawal of the filter body, the filter body having a proximal end and a distal end and being movable between an elongate collapsed delivery and/or withdrawal configuration and a deployed expanded position, the delivery system comprising an elongate guide, a distal end of the filter being mounted on the guide and the proximal end of the filter body being mounted on an actuator, the actuator being movable relative to the guide for movement of the filter body between the collapsed and deployed position.

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Preferably the filter element is remotely actuatable by sliding a rod inside a tube such that the ends of the filter are moved apart to achieve a low radial profile for positing the filter and are moved towards each other to deploy the filter.

- 6 -

In one embodiment of the invention the actuator comprises a tube which is slidable over the guide for movement of the filter body between the collapsed and deployed configurations.

5 Preferably the guide is an elongate guidewire.

In a preferred arrangement the port is angled on the body to direct the medical device towards the distal outlet end of the body.

10 Ideally the included angle between an axis of the bore and an axis of the port is less than 60° , preferably the included angle between an axis of the bore and an axis of the port is approximately 30° .

15 In another aspect the invention provides an embolic protection device comprising a filter body and a delivery system for delivery and/or withdrawal of the filter body, the filter body having a proximal end and a distal end and being movable between an elongate collapsed delivery and/or withdrawal configuration and a deployed expanded position, the delivery system comprising an elongate guide, a distal end of the filter being mounted on the guide and the proximal end of the
20 filter body being mounted on an actuator, the actuator being movable relative to the guide for movement.

25 Preferably the actuator comprises a tube which is slidable over the guide for movement of the filter body between the collapsed and deployed configurations.

Most preferably the guide is an elongate guidewire.

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- 7 -

Brief Description of the Drawings

The invention will be more clearly understood from the following description thereof, given by way of example only, with reference to the accompanying
5 drawings, in which:-

Fig. 1 is an elevational view of a surgical shunt according to the invention;

10 Fig. 2 is a perspective view illustrating the surgical shunt in use mounted in an artery;

Fig. 3 is an elevational view of a vascular filter delivery catheter in use with the shunt;

15 Fig. 4 is a perspective view of a delivery pod of the catheter of Fig. 3;

Fig. 5 is a perspective, partially cut-away view, showing the shunt with a filter system deployed;

20 Fig. 6 is a perspective view of the surgical shunt in place with one end of the shunt removed from the artery with the filter still in place;

Fig. 7 is a perspective view showing the surgical shunt fully removed from the artery with the filter still in place;

25 Fig. 8 is a perspective partially cut-away view of a shunt according to another embodiment of the invention;

30 Fig. 9 is a perspective cut-away view of part of the shunt of Fig 8;

- 8 -

Fig. 10 is a partially sectional elevational view of an embolic protection device used with the shunt of the invention;

5 Fig. 11 is a schematic sectional elevational view of the embolic protection device of Fig. 10; and

Fig. 12 is a detailed sectional view of portion of the device of Figs. 10 and 11.

10 Fig. 13 is a detailed perspective view showing a filter element according to the invention;

Fig. 14 is a perspective view of the filter element of Fig. 13, in a collapsed position.

15

Description of the Invention

20 Referring to the drawings and initially to Figs 1 to 12, there is illustrated a surgical shunt according to the invention, indicated generally by the reference number 1. The shunt 1 has a tubular body 2 with an internal bore 3 extending between a proximal inlet end 4 and a distal outlet end 5. Sealing rings 6, 7 are provided adjacent each end 4, 5, of the body 2. A port 9 is provided intermediate the ends 4, 5, of the body 2 in a sidewall of the body 2 communicating with the bore 3 for delivery of a medical device into the bore 3. It will be noted that the port 9 is angled on the body 2 such that the included angle between an axis of the bore 3 and an axis of the port 9 is about 30°. A luer attachment 10 is mounted at a free outer end of the port 9 such that it may be connected to other medical equipment.

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- 9 -

Referring to Fig. 3, a surgical filter system according to the invention for use with the shunt 1 comprises a catheter 14 having an expandable pod 15 at a distal end of the catheter 14 for reception of an expandable filter element 16 (Fig. 5). The filter element 16 is carried on a guidewire 17 which is slidably movable through the catheter 14. The filter element 16 is shown in the form of an expanded thin wall cylindrical element, but may equally be of any other constructions such as those described in our pending PCT Patent Application No. IE 98/00093 filed November 9, 1998, the entire contents of which are incorporated by reference. The filter 16 has enlarged proximal openings 18 to allow the flow of blood and embolic material to enter the filter element 16 and narrow distal openings 19 which allows through passage of blood while ensuring undesired emboli are captured within the filter element 16. A flexible tip 20 at the distal end of the filter element 16 aids in guiding the filter element to a desired deployment site within an artery 21.

Referring in particular to Fig. 3, the expandable pod 15 has tapered reinforcing legs 24 covered in a softer elastic material 25 forming the cylindrical pod for reception of the filter element 16. Thus, to retrieve the filter element 16, the pod 15 will expand to accommodate the filter element 16 which contains any captured emboli.

In more detail and referring to Figs. 10 to 12 there is illustrated an embolic protection device 100 which may be used with the shunt of the invention. The device 100 has a guidewire 101 with a proximal end 102 and a distal end 103. A tubular sleeve 104 is slidably mounted on the guidewire 101. A collapsible filter 105 is mounted on the sleeve 104, the filter 105 being movable between a collapsed stored position against the sleeve 104 and an expanded position as shown in the drawings extended outwardly of the sleeve 104 for deployment in a blood vessel.

- 10 -

The sleeve 104 is slidable on the guidewire 101 between a pair of spaced-apart end stops, namely an inner stop 106 and an outer stop which in this case is formed by a spring tip 107 at the distal end 103 of the guidewire 101.

5 The filter 105 comprises a mesh net 110 mounted over a collapsible support frame 111. The mesh net 110 is gathered in the sleeve 104 at each end, the net 110 being rigidly attached to a proximal end 112 of the sleeve 104 and the net 110 being attached to a collar 115 which is slidable along a distal end 114 of the sleeve 104. Thus the distal end of the net 110 is longitudinally slidable along the sleeve 104.
10 The support frame 111 is also fixed at the proximal end 112 of the sleeve 104. A distal end 116 of the support frame 111 is not attached to the sleeve 104 and is thus also free to move longitudinally along the sleeve 104 to facilitate collapsing the support frame 111 against the sleeve 104. The support frame 111 is such that it is naturally expanded as shown in the drawings and can be collapsed inwardly
15 against the sleeve 104 for loading in a catheter 118 or the like.

20 The filter 105 has large proximal inlet openings 117 and small distal outlet openings 119. The proximal inlet openings 117 allow blood and embolic material to enter the filter body, however, the distal outlet openings 119 allow through passage of blood but retain undesired embolic material within the filter body.

25 An olive guide 120 is mounted at a distal end of the sleeve 104 and has a cylindrical central portion 121 with tapered ends 122, 123. The distal end 122 may be an arrowhead configuration for smooth transition between the catheter and olives surfaces. The support frame 111 is shaped to provide a circumferential groove 125 in the filter net 110. If the filter is too large for a vessel, the net may crease and this groove 125 ensures any crease does not propagate along the filter.

30 Enlarged openings are provided at a proximal end of the filter net 110 to allow ingress of blood and embolic material into an interior of the net 110.

- 11 -

In use, the filter 105 is mounted in a collapsed state within a distal end of the catheter 118 and delivered to a deployment site. When the filter is correctly positioned the catheter 118 is retracted allowing the support frame 111 to expand inflating the net 110 across the vessel in which the filter is mounted. Blood and emboli can enter the enlarged openings at a proximal end of the net 110. The blood will pass through the net wall, however, the openings or pores in the net are sized so as to retain the embolic material. After use the catheter is delivered along the guidewire 101 and slid over the filter 105 engaging the proximal inlet 112 first to close the openings and then gradually collapsing the net against the sleeve 104 as the catheter 118 advances over the filter 105. Once the filter 105 is fully loaded in the catheter 118, it can then be withdrawn.

It will be noted that a proximal end of the filter is fixed and a distal end of the filter is longitudinally movable along the sleeve to facilitate collapsing of the filter net.

Further, the catheter engages the proximal end of the filter net first thus closing the filter net inlet and preventing escape of embolic material from the filter net as the filter net is being collapsed.

The outer filter body 110 is preferably of a resilient biocompatible elastomeric material. The material may be a polyurethane based material. There are a series of commercially available polyurethane materials that may be suitable. These are typically based on polyether or polycarbonate or silicone macroglycols together with a diisocyanate and a diol or diamine or alkanolamine or water chain extender. Examples of these are described in EP-A-461,375 and US 5,621,065. In addition, polyurethane elastomers manufactured from polycarbonate polyols as described in US 5,254,622 (Szycher) are also available.

The filter body may also be a biostable polycarbonate urethane article an example of which may be prepared by reaction of an isocyanate, a chain extender and a

- 12 -

polycarbonate copolymer polyol or alkyl carbonates. This material is described in our co-pending PCT Application No. IE98/00091, filed November 9, 1998, the entire contents of which are incorporated herein by reference.

5 In use, a surgical incision is made as per routine practice. A shunt 1 is placed as shown in Fig. 2 bridging opposite ends of a surgical incision 26 in the artery 21. The shunt 1 provides a pathway around the length of vessel 21 being treated. It is typically clamped in place with the clamp using the bulged section of the sealing rings 6, 7 on the shunt for purchase.

10 With the shunt 1 in place, the filter element 16 which in this case is bonded onto a guidewire element 17 is loaded into its delivery/retrieval catheter 14. The catheter 14 is extended through the luer attachment 10 and moved to a desired location downstream of the shunt 2. The filter 16 is deployed by pulling the
15 catheter 14 back relative to the filter 16 so that the filter element 16 is unsheathed and expands to engage the sidewalls of the artery 21 as shown in Fig. 5. The catheter 14 is then removed and the filter element guidewire 17 is sealed in the shunt 1 by way of locking a Tuohy-Borst connector 30 (Fig. 5) onto it. The fine guide wire 17 sitting in the shunt 1 ensures minimal impedance to flow through
20 the shunt 1.

The filter 16 in its deployed condition offers protection to the brain against embolic material passing through to the brain as the surgical procedure is performed.

25 At the conclusion of the procedure, the removal of the shunt 1 may be performed with the filter 16 in place and protecting against emboli. Ideally, the proximal end of the shunt is removed and a suture line 32 is brought up to the point where the distal end of the shunt enters the vessel (see Fig. 6). A retrieval catheter 14 is then
30 positioned over the guidewire and moved forward to a position with it's tip inside the carotid artery. The shunt 1 may then be brought back over the catheter until it

- 13 -

is outside the artery as illustrated in Fig. 7. With the shunt 1 removed, the catheter 14 is left in place for a period of time to allow the blood to flow to return to normal and the filter 16 to capture any embolic material that may pass through it.

5

The filter 16 is then pulled back into the retrieval catheter 14 which includes an expandable segment or pod 15 at its distal end to allow the pod to accommodate the filter 16 and retrieved material. See Fig. 3. After removal of the retrieval catheter 14 the wound may be closed off to complete the shunting procedure.

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Most importantly, the length of the external proximal portion of the mounting system is greater than the sum of the length of the entry port and the distal section of the shunt bore for removal of the distal section of the shunt body while maintaining the medical device in situ.

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Referring to Figs 8 and 9 there is illustrated another shunt 50 according to the invention. In this case the filter element 16 is housed at a distal end 51 of the shunt 50 and is introduced to the vasculature encapsulated by the distal portion 51 of the shunt 50. The filter 16 is deployed by advancing the guidewire 17 so that the filter 16 is released from the shunt. On release, the filter 16 expands and deploys downstream of the shunt 50 as illustrated in Fig. 5. In this way the distal portion 51 acts as a delivery device for the filter 16. On completion of the surgical procedure the shunt 50 is removed and the filter element 16 is retrieved using a retrieval catheter as described above.

20

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It will be appreciated that the filter 16 can be deployed prior to or at any stage during a surgical procedure. The filter 16 is placed in an artery, allows the blood to flow through it but captures and retains particulate matter being carried by the blood of a size greater than the filter pore size. In the particular embodiment described, the brain is protected during the surgical endarterectomy procedure by way of a filter 16 delivered through the shunt 1. The system allows the filter 16 to

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- 14 -

remain in situ not only during the surgical procedure but also as the shunt 1 is removed from the patient. The removal of the shunt is a critical event and one which can liberate embolic debris. It is known that a key time of risk is during the re-establishment of blood flow in the time period during and after shunt removal. Thus the invention provides a shunt which provides considerable advantages in assuring embolic protection during and after the surgical procedure.

Referring to Figs. 10 and 11, a construction of filter is shown. In this case, the filter element 16 has a distal end 40 which is attached adjacent an end of a guidewire 17. An inner proximal end 41 of the filter 16 is secured to a tubular sleeve 43 which is slidably mounted on the guidewire 17. By sliding the sleeve 43 along the guidewire 17 as indicated by arrow A in Fig. 8, the filter 16 can be moved between an expanded position as shown in Fig. 9 and an elongate collapsed position as shown in Fig. 10 having a low radial profile for delivery of the filter through a catheter to a deployment site.

The filter element 16 may be of a suitable shape memory material such as a Nitinol mesh or a suitable polymeric material such as those described above. Although the filter may be used in association with an suitable delivery/retrieval system it is particularly suitable for use with a shunt in which steerability is not usually a key issue as the distance that the filter travels through the vasculature is relative short and placement is controlled more readily.

The filter may be deployed/withdrawn using a catheter such as the catheter 14 described above.

The invention is not limited to the embodiments hereinbefore described with reference to the accompanying drawings.

- 15 -

Claims

1. A surgical shunt comprising:-

5 a tubular shunt body;

an entry port integral with the shunt body;

10 a medical device for delivery and/or retrieval through the entry port; and

a mounting system for the medical device;

15 the tubular shunt body having a bore with a proximal end and a distal section extending distally of the bore, the distal section having a distal end;

20 the entry port having an external proximal section and an internal distal end communicating with the distal section of the bore;

25 the medical device mounting system having a distal portion and a proximal portion, the external proximal portion of the mounting system lying substantially external of the bore;

30 the length of the external proximal portion of the mounting system being greater than the sum of the length of the entry port and the length of the distal section of the shunt bore for removal of the distal section of the shunt body while maintaining the medical device in situ.

- 16 -

2. A surgical shunt as claimed in claim 1 wherein the mounting system comprises a medical guidewire.
- 5 3. A surgical shunt as claimed in claim 2 wherein the mounting system includes a catheter for delivery and/or retrieval of the medical device, the guidewire being extendable through the catheter.
- 10 4. A surgical shunt as claimed in any of claims 1 to 3 wherein the medical device is an embolic protection device.
- 15 5. A surgical shunt as claimed in claim 4 wherein the embolic protection device comprises a filter body having:
 - a first collapsed configuration and a second expanded, deployed configuration;
 - 20 a proximal inlet section and a distal outlet section, said proximal inlet section including inlet openings which are operable to admit blood and embolic material when the filter is in the second expanded configuration; and
 - 25 a plurality of outlet openings disposed on at least a portion of the filter body adjacent to the distal outlet section, the outlet openings being sized to allow through passage of blood but to retain undesired embolic material within the filter body.
- 30 6. A surgical shunt as claimed in claim 5 wherein the filter body is mounted on a guidewire.

- 17 -

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7. A surgical shunt as claimed in claim 6 including a retrieval catheter, the guidewire being slidably movable through the catheter for retrieval of the filter element, the catheter having a pod at a distal end thereof for reception of the filter element in a collapsed state.
8. A surgical shunt as claimed in claim 7, wherein the pod is expandable.
9. A surgical shunt as claimed in claim 8, wherein the pod has a resiliently deformable sidewall.
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10. A surgical shunt as claimed in claim 9, wherein the pod comprises radially spaced-apart reinforcing legs covered in an elastic material.
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11. A surgical shunt as claimed in any of claims 4 to 10 wherein the embolic protection device comprises a filter body and a delivery system for delivery and/or withdrawal of the filter body, the filter body having a proximal end and a distal end and being movable between an elongate collapsed delivery and/or withdrawal configuration and a deployed expanded position, the delivery system comprising an elongate guide, a distal end of the filter being mounted on the guide and the proximal end of the filter body being mounted on an actuator, the actuator being movable relative to the guide for movement of the filter body between the collapsed and deployed position.
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12. A surgical shunt as claimed in claim 11 wherein the actuator comprises a tube which is slidable over the guide for movement of the filter body between the collapsed and deployed configurations.
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13. A surgical shunt as claimed in claim 11 or 12 wherein the guide is an elongate guidewire.
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- 18 -

14. A surgical shunt as claimed in any preceding claim, wherein the port is angled on the body to direct the medical device towards the distal outlet end of the body.
- 5 15. A surgical shunt as claimed in claim 14, wherein the included angle between an axis of the bore and an axis of the port is less than 60°.
16. A surgical shunt as claimed in claim 14 wherein the included angle between an axis of the bore and an axis of the port is approximately 30°.
- 10 17. A surgical shunt as claimed in any preceding claim wherein the medical device is housed in the distal section of the tubular shunt body.
- 15 18. A surgical shunt substantially as hereinbefore described with reference to the accompanying drawings.
19. An embolic protection device comprising a filter body and a delivery system for delivery and/or withdrawal of the filter body, the filter body having a proximal end and a distal end and being movable between an elongate collapsed delivery and/or withdrawal configuration and a deployed expanded position, the delivery system comprising an elongate guide, a distal end of the filter being mounted on the guide and the proximal end of the filter body being mounted on an actuator, the actuator being movable relative to the guide for movement of the filter body between the collapsed and deployed position.
- 20 25 20. A device as claimed in claim 19 wherein the actuator comprises a tube which is slidable over the guide for movement of the filter body between the collapsed and deployed configurations.
- 30

- 19 -

21. A device as claimed in claim 19 or 20 wherein the guide is an elongate guidewire.

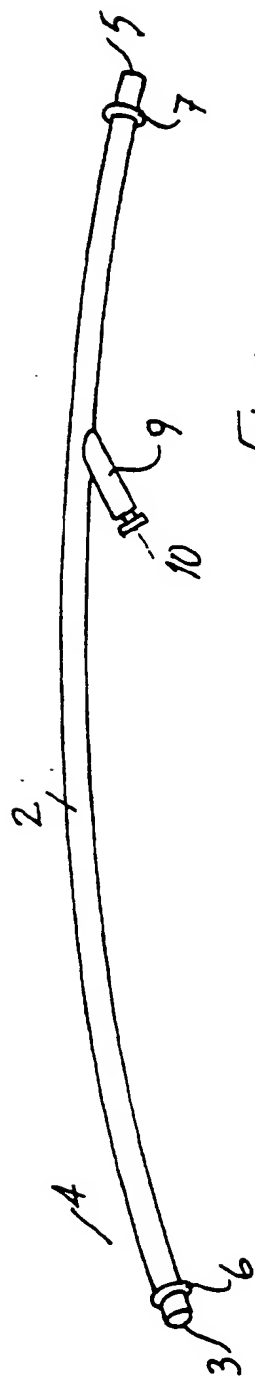


Fig. 1

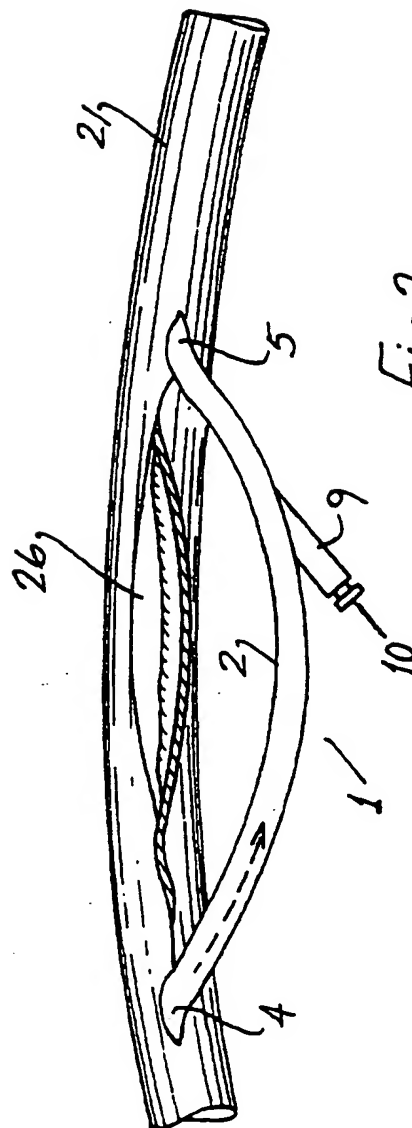
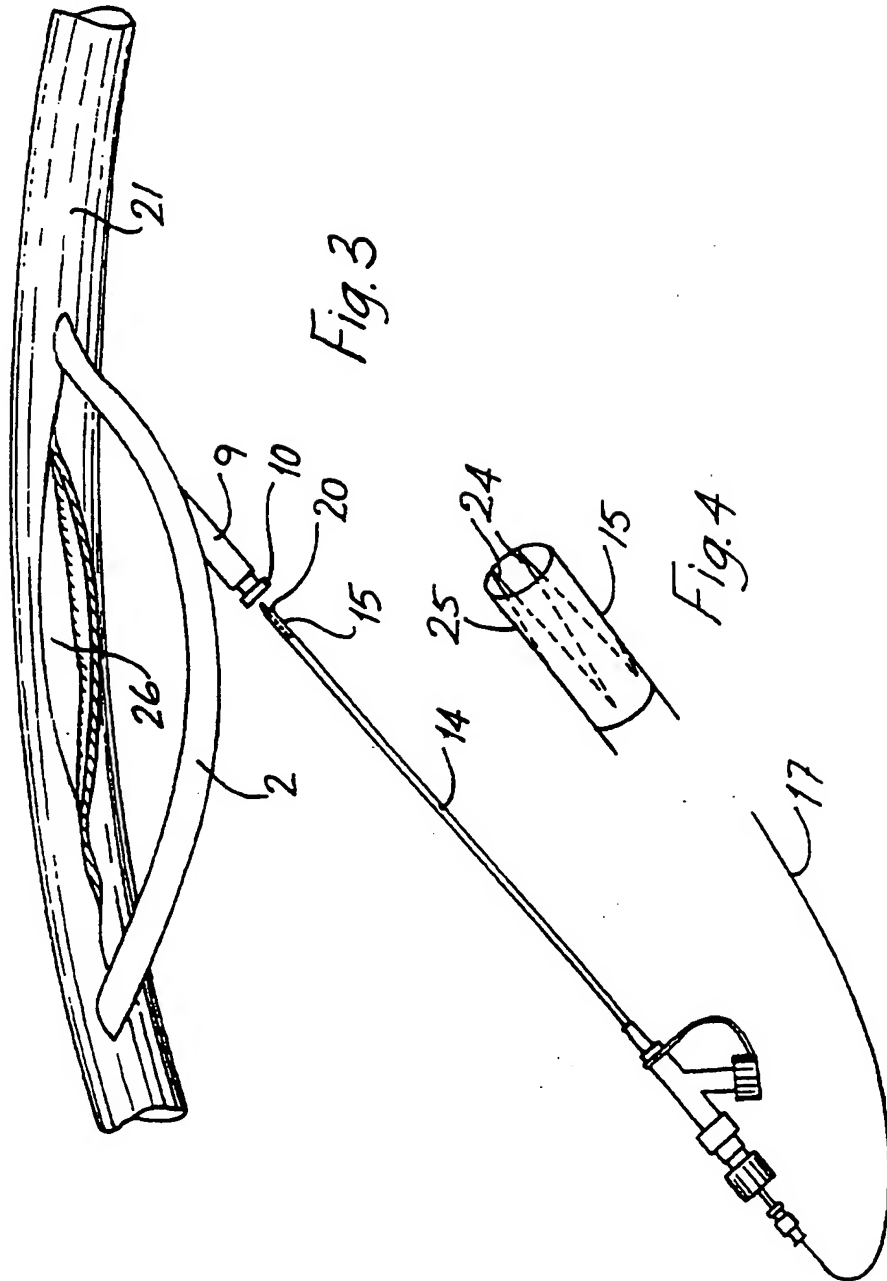


Fig. 2



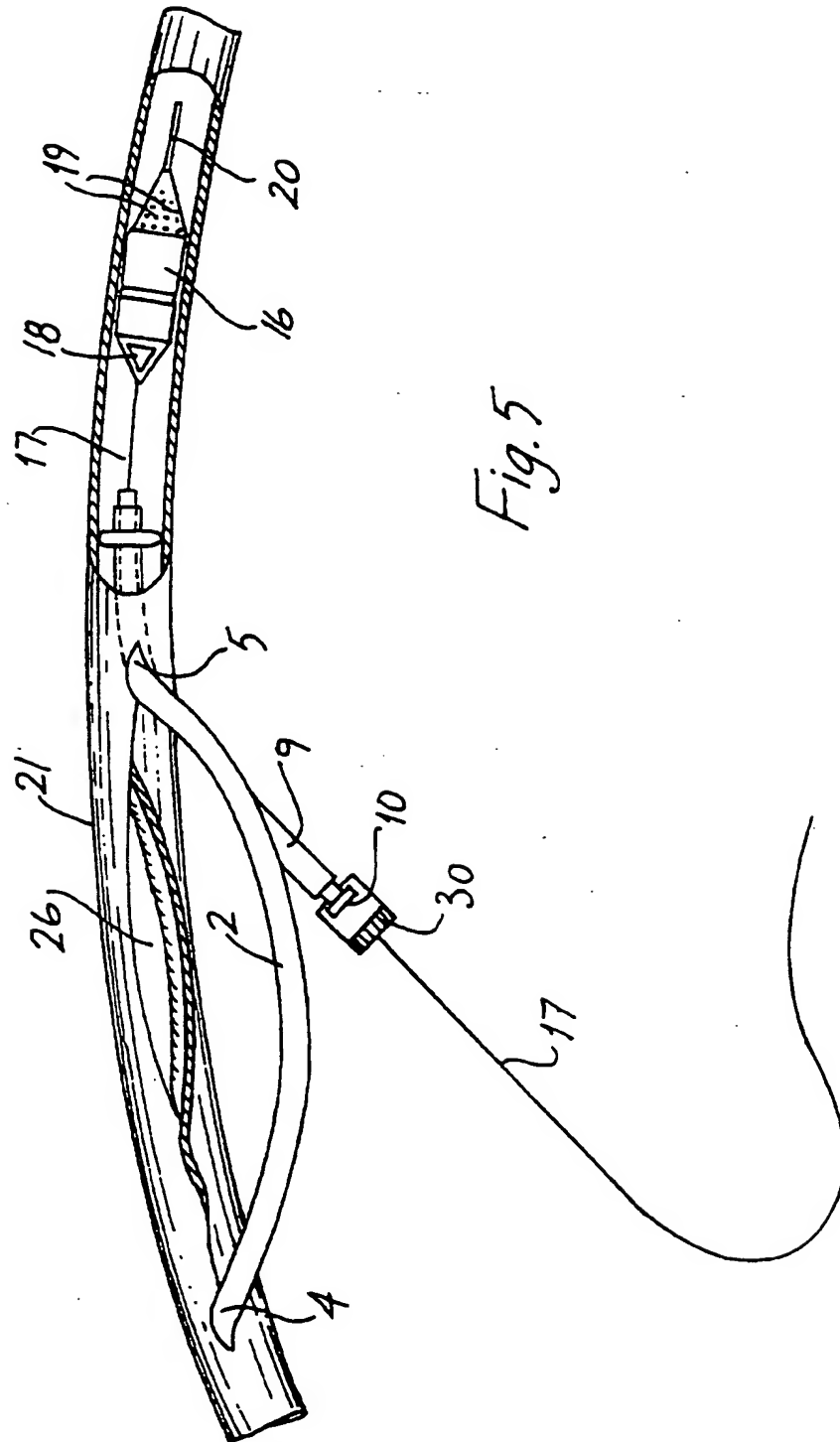


Fig. 5

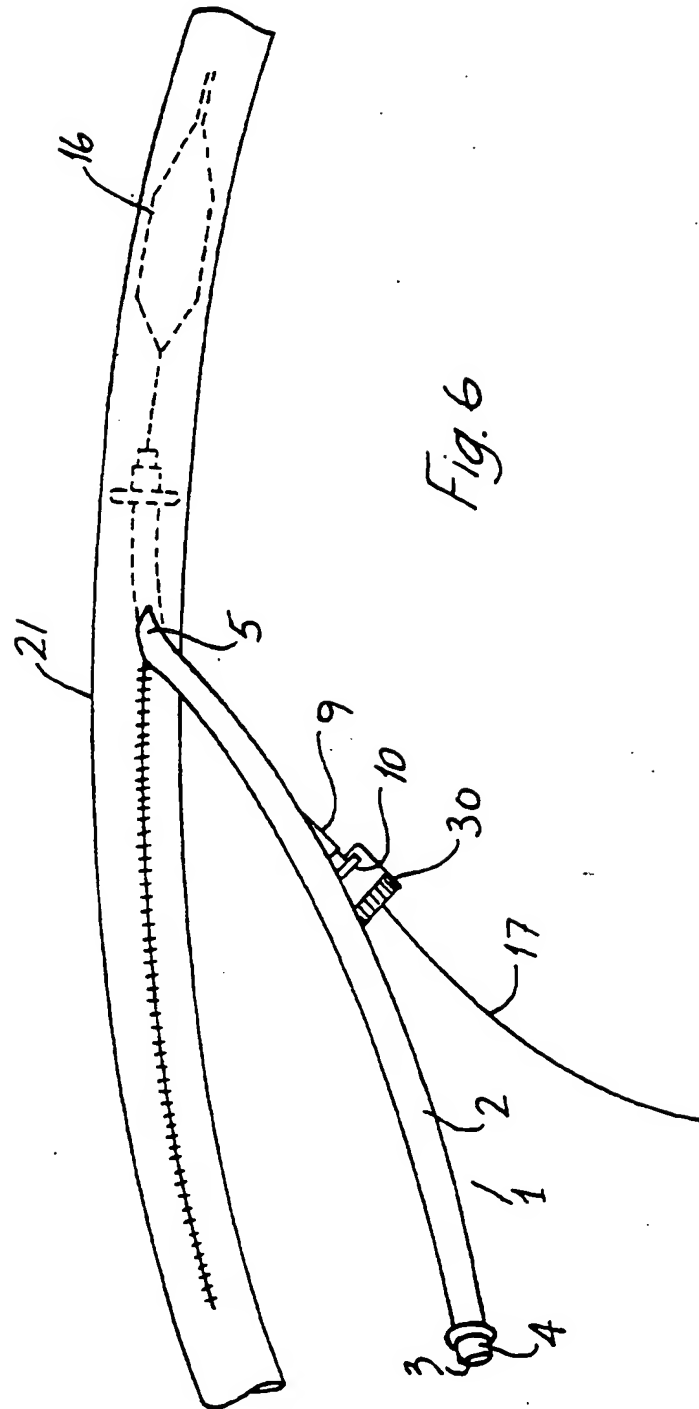


Fig. 6

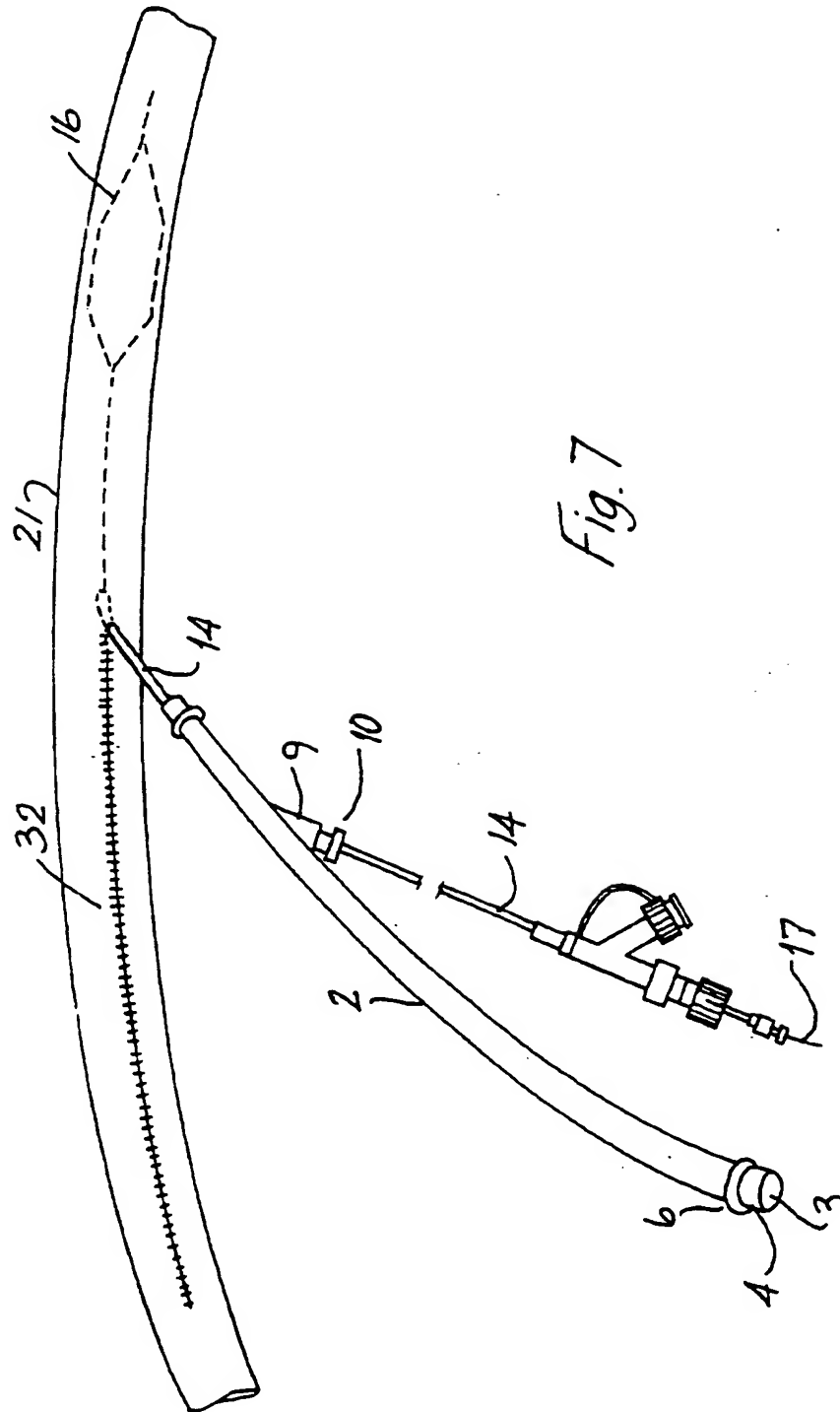
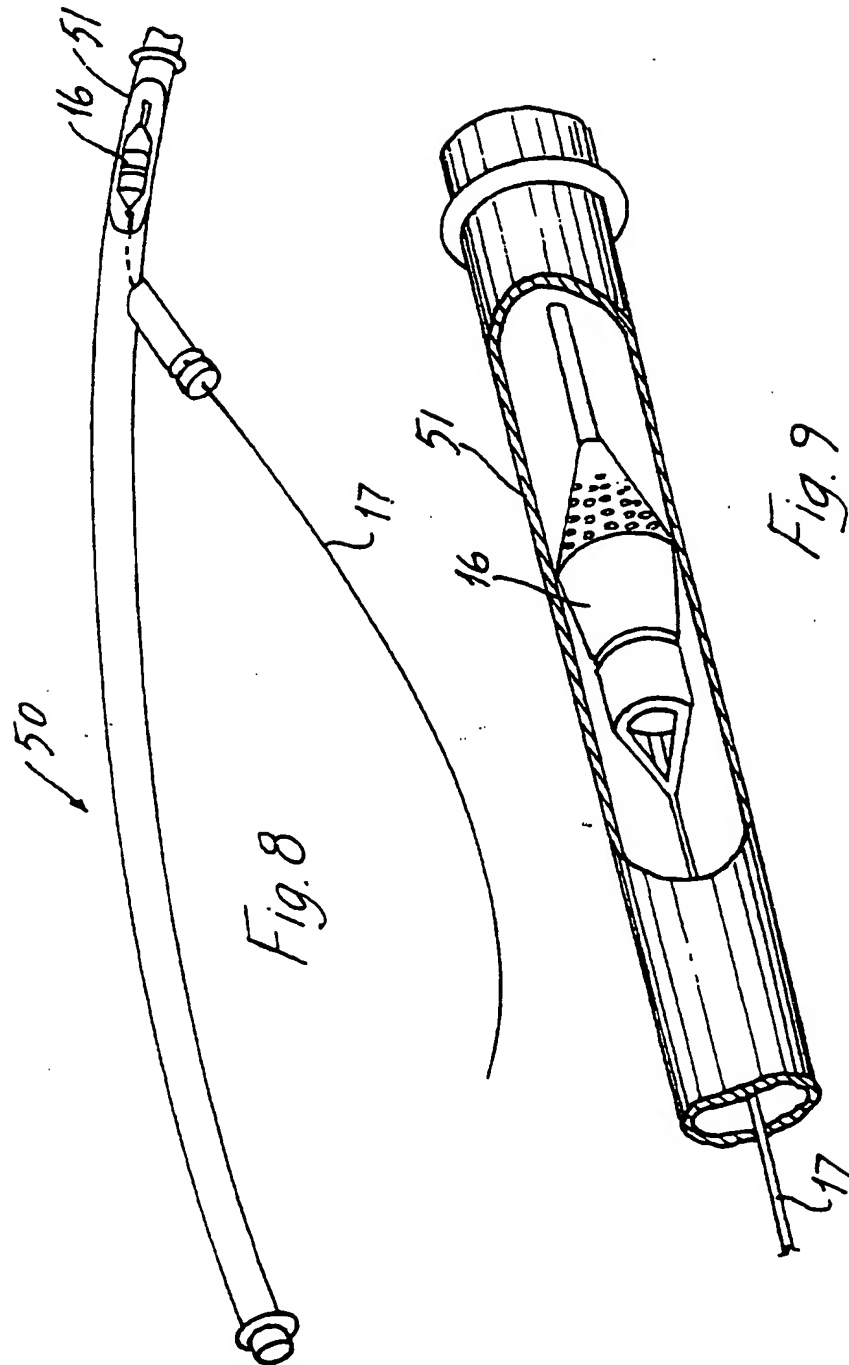


Fig. 7



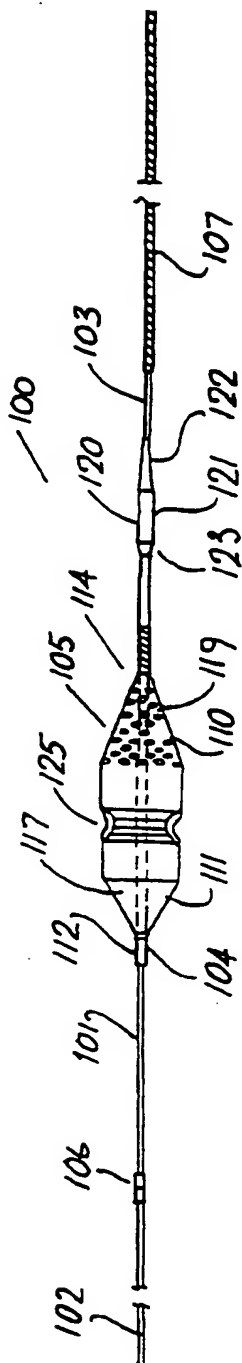


Fig.10

